

NOV 17 2005

Stockert GmbH**510(k) Summary**August 19th, 2005

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This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Contact: Dominika Schuler, Management Representative

Trade Name: Stimuplex® HNS 12

Common Name: Battery powered peripheral Nerve Stimulator

Classification Name:

Anesthesiology Devices, Class II, 73 BXN
Battery Powered Nerve Stimulator
21 CFR 868.2775

Predicate Device: Stimuplex® HNS 11
K003983

The nerve stimulator Stimuplex® HNS 12 is a battery powered peripheral nerve stimulator for localization of nerve fibers in the tissue. During the operation the operating physician holds a stimulation cannula in his right hand. Simultaneous the operation of the device happens with his left hand. The physician can hold the device with the left hand and simultaneous alter the stimulation amplitude at the amplitude controller.

The technical data of the device are:

Battery:	9 Volt alkaline
Display:	1 graphic LCD Module
Operation:	1 tricolor (green, yellow, red) LED for status display
	1 control button to switch on/off the device
	Adjustment knob to adjust the wanted stimulation current
	3 control buttons to switch the stimulation parameters
	4 control buttons for navigation and settings in the menus
	Remote control (optional stimulation current adjustment)
Power consumption:	6 mA (8 mA max in warning/alarm state)
Stimulation current :	max. 5mA / 0Ω - 12 k Ω
Stimulation voltage :	max. 95 Vpp
Stimulation frequency :	1 Hz / 2 Hz
Flowing current	
measuring tolerance:	+/- 0.02 mA
Weight:	0.25 kg (with battery)

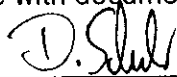
The configuration of the electrode connection is realized with a 4 pin plug connection system, which ensures correct polarity of the electrode at all times. The Stimuplex® HNS 12 generates negative, current-stabilized square pulses with selectable frequency, selectable pulse width and fine adjustable stimulation current. The pulse is shaped at both slopes by extremely fast active pulse drivers. An output amplifier specially designed for this application has an extraordinarily wide dynamic range and produces reproducible settings even below 0.1 mA. The stimulation frequency and the pulse width can be varied for different applications. The Stimuplex® HNS 12 nerve stimulator offers the facility for selecting a frequency of either 1 Hz or 2 Hz together with pulse widths of 0.1 ms, 0.3 ms or 1.0 ms. Two additional pulse widths: 0.05 ms and 0.50 ms can be enabled in options menu. Stimuplex® HNS 12 has a menu structure (in 26 languages) where the switch on parameters and options and setup parameters like tone volume, contrast, automatically switch off time, language can be configured. The battery voltage is in info menu in volt and percentage and during stimulation menu as symbol displayed.

The intended use is a peripheral nerve stimulator to test the level of pharmacological effect of anesthetic drugs and gases to the patient and/or as a nerve locator for the verification of needle placement for the application of local anesthetics. This device can be used wherever peripheral anesthesia is normally applied (i.e. physicians office or hospital). There are no known contraindications for the use of this device on any patient population.

The general technological characteristics of the Stimuplex® HNS 12 are generally equivalent in materials, form and intended use to the Stimuplex® HNS 11 Peripheral Nerve Stimulator. Differences between the Stimuplex® HNS 12 and the predicate device consist in the additional functions for Stimuplex® HNS 12: load impedance measurement, electrical charge display, menu structure in 26 languages. The Stimuplex® HNS 12 is high specific for its intended use in the anaesthesiology. The differences don't affect safety and effectiveness for the intended use.

All finished products are tested and must meet all required release specifications before distribution. The array of testing required for release include, but are not limited to: physical testing, visual examination (in process and finished product). The physical testing is defined by Quality Control Test Procedure documents. These tests are established testing procedures and parameters which conform to the product design specifications. The testing instruction records for each of the individually required procedures are approved, released, distributed and revised in accordance with document control GMP's.

signed: _____



Dominika Schuler, Management Representative
Stockert GmbH

date: 2005-08-23



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Dominika Schuler
Management Representative
Stockert GmbH
Boetzinger, Strasse 72
Freiburg, B-W
GERMANY D-79111

Re: K052313

Trade/Device Name: Stimuplex HNS-12
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: II
Product Code: BXN
Dated: August 23, 2005
Received: August 31, 2005

Dear Ms. Schuler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

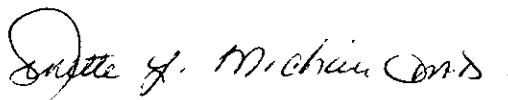
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-___. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", is written over a horizontal line.

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052313

Device Name: Stimuplex HNS-12

Indications For Use:

Stimuplex HNS-12 is a peripheral nerve stimulator used to test the level of pharmacological effects of anesthetic drugs and gases to the patient and/or as a nerve locator for the verification of needle placement for the application of local anesthetics. This device can be used wherever peripheral anesthesia is normally applied (i.e. physicians office or hospital).

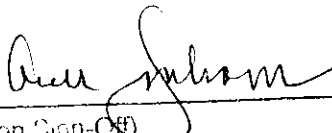
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division Sign-Off
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K052313

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